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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,439	11/14/2001	Frank Pfluecker	BARD-1	6767

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[REDACTED] EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<h2 style="margin: 0;">Office Action Summary</h2>	Application No. <b>09/987,439</b>	Applicant(s) <b>Pfluecker et al.</b>
	Examiner <b>Deepak Rao</b>	Art Unit <b>1624</b>
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b>		
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p>		
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Apr 4, 2003</u>		
2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
<b>Disposition of Claims</b>		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-21</u> <input checked="" type="checkbox"/> /are pending in the application.		
4a) Of the above, claim(s) _____ <input checked="" type="checkbox"/> /are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ <input checked="" type="checkbox"/> /are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>1-21</u> <input checked="" type="checkbox"/> /are rejected.		
7) <input type="checkbox"/> Claim(s) _____ <input checked="" type="checkbox"/> /are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
<b>Application Papers</b>		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
13) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) <input checked="" type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input checked="" type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
*See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
<b>Attachment(s)</b>		
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>3</u>		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____		

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## **DETAILED ACTION**

Claims 1-21 are pending in this application.

### *Election/Restriction*

Applicant's election with traverse of Group I, claims 1-12 and 15-21 drawn to compounds of formula I wherein X is O in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the restriction is improper. This is not found persuasive because the inventions of Groups I-III are drawn to structurally dissimilar compounds that have different patentability issues. For example, a reference anticipating a benzopyran derivative according to Group I, may not render obvious a compound according Group II or III. Further, the compounds according to each of the groups are classified separately and they require separate burdensome searches in the literature and patent databases. Therefore, the compounds of formula I for different values of X do involve a burdensome search in all the databases and literature. The compounds of Groups I-III do not form a single inventive concept within the meaning of 35 U.S.C. 121 because a reference that anticipates or renders obvious one of the groups would not necessarily render obvious the other group and applicants have not clearly stated on the record that this is not the case. Further, 37 CFR 1.141(a) provides that two or more independent and distinct inventions may not be claimed in one application, whether or not the misjoinder occurred in one claim or more than one claim. Restriction is going to be exercised where independent and distinct inventions are presented in one Markush grouping. Independent means when the compound is being made and/or used

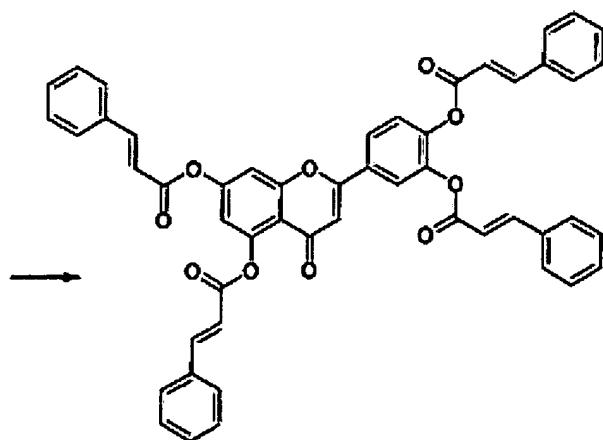
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alone, not in combination with other compounds of the Markush expression. Therefore, what should be considered for patentable distinctness is the compound as a whole.

Applicant further urges that each of the inventions of Groups I-III and IV-VI respectively are not related as two subcombinations. Applicant indicates that Group I and Group IV are related as compound and composition containing the compound, similarly Groups II & V; and Groups III and VI. This argument is found to be persuasive and Groups IV-VI are rejoined with corresponding Groups I-III (i.e., Groups I & IV; Groups II & V; and Groups III & VI are joined together). Accordingly, claims 13-14 incorporated into each of Groups I-III and will be examined to the extent of the elected invention of compounds of formula I wherein X is O.

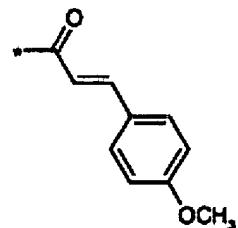
The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of the species of Example 5 (as disclosed in page 25 of the specification) is acknowledged. The elected species is depicted below for convenience:



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The elected species does not read on any of the claims. The compounds of independent claims 1 and 2 require that at least one of the groups R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup> and R<sup>5</sup> is -OA and the A group that comes closest to the elected species is:



The guidelines in MPEP § 803.02 provide that upon examination if prior art is found for the elected species, the examination will be limited to the elected species.

Content of MPEP § 803.02 is provided here for convenience:

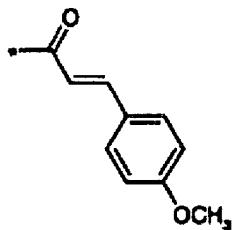
As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the merits on the elected claims would be final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that

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anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

As none of claims read on the elected species, the search was conducted to cover compounds of formula I wherein at least one of groups R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup> and R<sup>5</sup> is -OA and the A group is



and art was found. As per the guidelines above, claims 1-21 (in part) drawn to compounds of formula I wherein A is other than the above moiety, are withdrawn from consideration by the examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected species.

#### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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1. In claim 1, line 1, in the preamble “A compounds...”, the plural recitation is improper. Replacing with -- compound -- is suggested.
2. In claims 1 and 2, in the last line, the phrase “formed by” is confusing and redundant. The claims reads better without this phrase.
3. In claim 2, line 10, “in addition, R<sup>1</sup>..... of one another, **can stand for a**” does not appear to be in acceptable claim language. Replacing the phrase “can stand for” with --optionally represent -- is suggested.
4. The structural formula in claim 3 shows a substituent R<sup>6</sup> at 3-position, however, there is no definition provided for this term. Further, there is insufficient antecedent basis for this limitation in claim 1 on which claim 3 is dependent. The base claim has a substituent R<sup>5</sup> at 3-position, see formula I in claim 1.
5. The structural formula II in claim 4 shows a substituent R<sup>6</sup> at 3-position, however, there is no definition provided for this term. Further, there is insufficient antecedent basis for this limitation in claim 2 on which claim 4 is dependent. The base claim has a substituent R<sup>5</sup> at 3-position, see formula I in claim 2.
6. The recitation “**in particular**” at line 2 of claims 11 and 12 is not acceptable. It appears the claim contains the broad and narrow limitations.
7. Claims 17-20 provide for the use of the compounds, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is

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intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 U.S.C. § 101***

Claims 17-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 13-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin et al., CAPLUS Abstract 131:58671 (1999). The instantly claimed compounds read on the reference disclosed compound, see the compound of RN 228405-91-2 in the enclosed copy of the CAPLUS search report.

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***Duplicate Claims***

Applicant is advised that should claims 1 and 2 be found allowable, claims 15 and 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Receipt is acknowledged of the Information Disclosure Statement filed on January 15, 2002 and a copy is enclosed herewith.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Deepak Rao  
Primary Examiner  
Art Unit 1624

June 16, 2003